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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,450	11/27/2001	Keun-Ho Lee	2008-3-14	2210

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EXAMINER

LEE, EDMUND H

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/995,450

Applicant(s)

LEE, KEUN-HO

Examiner

EDMUND H. LEE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The substitute specification filed 6/30/03 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: it is replete with new matter. The following are examples of new matter found in the marked-up copy of the substitute specification: "drain body fluid" (pg 1, ln 18; the scope is not supported); "substantially obviates" (pg 9, ln 1; the original specification support obviating the problems of the conventional processes); "the mold lubricant *must* be coated...by a round" (pg 13, lns 22-24; the criticality has not been presented in the substitute specification); "boundary surface *must* be formed as a straight line" (pg 14, ln 1; the criticality has not been presented in the substitute specification); "the second tube must be maintained uniformly...does not deteriorate" (pg 14, lns 15-17; the criticality has not been presented in the substitute specification); "Preferably, two inflation apertures...respectively" (pg 16, lns 18-20; the scope is not supported. The original specification supports and enables only two apertures); "inflation apertures...may avoid" (pg 16, ln 24; scope not supported. The reduced sizes avoids the problem); "Thereafter...straight" (pg 17, lns 2-6; scope not supported); "The secondary...coated" (pg 18, lns 2-4; scope not support and description is inaccurate). It should be noted that the above list is not a complete list of all the new matter found in the substitute specification. **APPLICANT IS CAUTIONED AGAINST THE INSERTION OF ADDITIONAL NEW MATTER INTO THE SPECIFICATION.**

2. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Coating the mold lubricant only to a portion punched the balloon injection opening in the first tubing while turning the circumference of the

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outer surface of the first tube (pg 13, lns 23-24) is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant specification discloses the criticality of the above step by using the words "must" and "only".

3. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Forming the coating boundary surface as a straight line (pg 14,ln 1) is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant specification discloses the criticality of the above step by using the words "must".

4. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The second tube having a uniform thickness (pg 14, lns 15-16) is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant specification discloses the criticality of the above step by using the words "must".

5. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Ensuring the coating portion of the mold lubricate does not discolor or the characteristic of the mold lubricant does not deteriorate (pg 14, lns 16-17) is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356

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(CCPA 1976). The instant specification discloses the criticality of the above step by using the words "required".

6. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Extruding an elongated lumen that has an outer diameter slightly smaller than the diameter of the desired finished catheter is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant specification discloses that the lumen must be slightly smaller than the finished catheter in order to produce a catheter that does not create pain when inserted. There is no step in the catheter.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Forming apertures with a diameter of about 0.5mm (pg 13, Ins 11-20) is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The instant specification discloses that the apertures must be smaller than conventional apertures, i.e., the diameter of the aperture is about 0.5mm), in order to symmetrical expansion and to prevent breakage.

8. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

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possession of the claimed invention. The claims introduce new matter into the disclosure. The added material which is not supported by the original disclosure is as follows:

a) the phrase "forming one or more apertures" (cl 1, ln 18) lacks support in the instant specification. There is support for only two apertures.

b) the phrase "forming a drainage hole" (cl 1, ln 29) lacks support in the instant specification. There is support for only a urine drainage hole.

c) the phrase "the one or more apertures" (cl 6, ln 1) lacks support in the instant specification. There is support for only two apertures.

9. Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "the balloon forming region" (cl 1, lns 18-19) lacks antecedent basis in the claim.

The phrase "connecting a plurality...more connectors" (cl 1, ln 23) is indefinite because it is confusing. It is unclear if the unit length lumen tubes connected are the unit length lumen tubes having the bond preventing agent coated thereon at the apertures at the balloon forming region. If they are then it should be positively and clearly recited as such. From the instant specification, the tubes connected should have the bond preventing agent coated thereon at the apertures at the balloon forming region.

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The phrase "extruding a balloon tube on the series" (cl 1,ln 24) is indefinite because it is confusing. The balloon tube should be extruded over the series such that the outer surface of the first tube is within the balloon tube.

The phrase "cutting...a plurality of unit length balloon tubes" (cl 1, ln 26) is indefinite because it is confusing as to what makes up a unit length balloon tube. If it is the unit length lumen tube having the bond preventing agent coated thereon bonded to a portion of the balloon tube then it should be clearly and positively recited as such.

The phrase "forming a drainage hole through the unit length balloon tube" (cl 1, ln 29) is indefinite because it is unclear whether or not the hole extends into the unit length lumen tube. The drainage hole must extend into the unit length lumen tube in order to allow the urine to flow through the catheter.

The phrase "a balloon forming region" (cl 8, ln 2) is indefinite because it is confusing as to whether or not it is related to the balloon forming region mention in claim 1 at lines 18 and 20. If they are the same then it should be clearly and positively recited as such.

Correction is required. Applicant is cautioned against the insertion of new matter.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to EDMUND H. LEE whose telephone number is 703.305.4019. The examiner can normally be reached on **MONDAY-THURSDAY FROM 9AM-4PM**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Colaianni can be reached on 703.305.5493. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0661.


EDMUND H. LEE 9/17/02
Primary Examiner
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EHL